



11-16-05

PATENT APPLICATION

AF/IFW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
Before the Board of Patent Appeals and Interferences

Applicant(s): Doherty, et al

Serial No.: 10/775,980

Group Art Unit No.: 1625

Filed: February 9, 2004

Examiner: Morris, Patricia L.

For: VANILLOID RECEPTOR LIGANDS AND THEIR USE IN TREATMENTS

Docket No.: A-824

LETTER TRANSMITTING BRIEF FOR DOHERTY, et al

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Enclosed are three copies of the BRIEF FOR DOHERTY, ET AL in the matter of this appeal. Please charge Deposit Account No. 01-0519 in the amount of \$500.00 (37 CFR 41.20(b)(2)) to cover the cost of filing the Brief. An original and one copy of this paper are enclosed.

The Commissioner is hereby authorized to charge any additional fees, which may be required, or credit any overpayment to Deposit Account No. 01-0519. An original and one copy of this paper are enclosed.

Respectfully submitted,

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Attorney/Agent for Applicant(s)
Registration No.: 42,991
Phone: (805) 447-3299
Date: November 14, 2005

Please send all future correspondence to:

21069

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EXPRESS MAIL CERTIFICATE

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Dee Dee Sutherland

Printed Name

Signature



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APPEAL BRIEF

Real Party in Interest

Amgen Inc.

Related Appeals and Interferences

None

Status of Claims

Claims 7 and 9 stand rejected.

Claims 1, 6, 11, 14-17 and 20 are objected to.

Claims 1 and 6-20 are on appeal.

Summary of the Invention

The invention relates to compounds useful as vanilloid receptor antagonists.

Issues

I. Is Claim 1 properly objected to as containing non-elected subject matter?

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II. Were Claims 7 and 9 properly rejected under 35 U.S.C. § 112?

III. Were Claims 8, 10, 12, 13, 18 and 19 properly withdrawn from consideration as being drawn to non elected subject matter under 37 CFR § 1.142(b)?

Argument

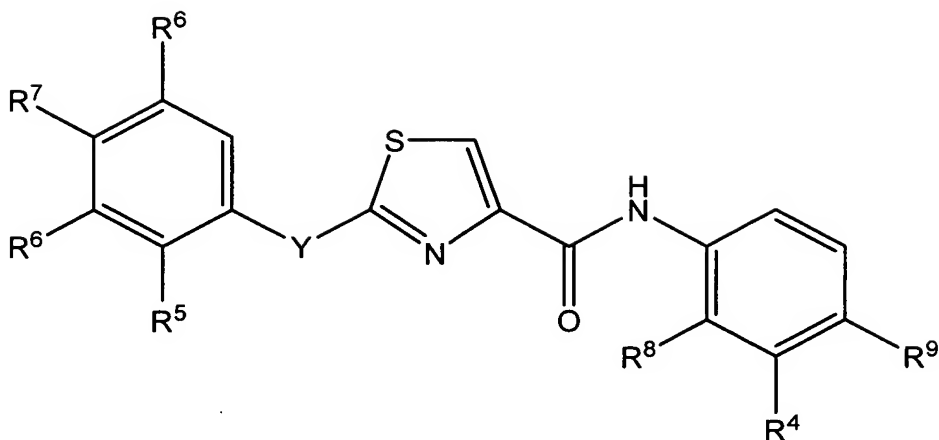
I. Is Claim 1 properly objected to as containing non-elected subject matter?

The Office Action of March 24, 2005 objects to Claim 1 as containing non-elected subject matter.

A first Office Action dated July 29, 2004, provided for a restriction requirement between two groups. Group I, which included “Claims 1-6 [sic], drawn to compounds, . . .”, and Group II, which included “Claims 3-5, drawn to multiple uses, . . .”

In a response dated August 12, 2004, the Applicants elected Group I, and proposed Example 3 from the specification as a representative species for examination.

In a second Office Action, dated October 22, 2004, the Office acknowledged the election of Group I, and the species of Example 3. The Office expanded the scope of the examination from the species (Example 3) to a sub-genus having the following generic structure:



and rejected compound Claims 1 and 6 as obvious over U.S. Patent No. 5,693,594, which contained compounds where the Y of the present claims was oxygen.

In a response dated January 14, 2005, the Applicants amended the claims to remove oxygen from the definition of Y, and added Claims 7-20 as compound claims depending from Claim 1. Having overcome all art rejections for Claims 1 and 6, the Applicants requested that the claims be allowed.

In a final Office Action dated March 24, 2005, the Office withdrew the § 103(a) rejection in light of the amendments to the claims. However, the Office objected to Claim 1 as being drawn to non-elected subject matter. Claims 6, 11, 14-17 and 20 were likewise objected to, but held to be allowable if rewritten in independent form. The Applicants respectfully believe that the imposition of the Office's sub-generic claim is improper given there is no outstanding prior art issues in the case.

A. The Office is imposing an improper restriction of the claims.

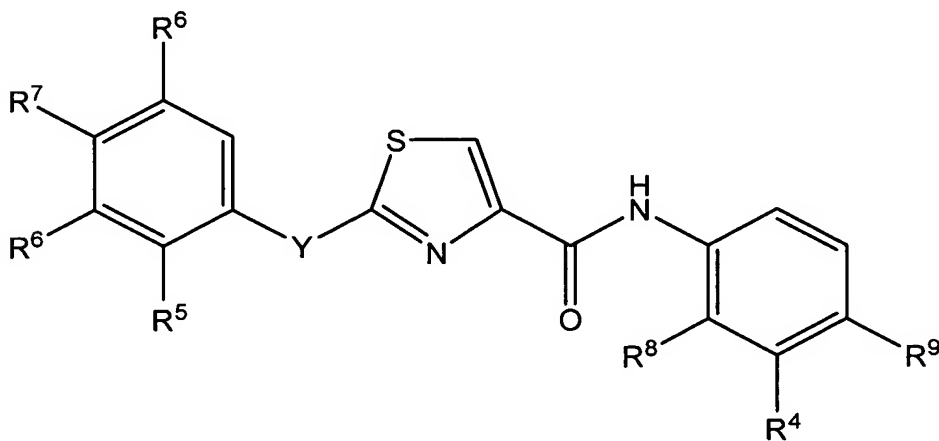
The Applicants elected Group I in response to the only restriction requirement presented by the Office in this case. Claims 1 and 6-20 all fall within the scope of Group I. The Applicants provided the Office with a species (Example 3) to assist with the examination, as requested. The Office provided a narrow sub-generic definition to facilitate their initial search. The Applicants amended the claims to remove all art within the scope of the Office's search. With no remaining prior art rejections, the Office should expand the

scope of the search to include more species, and if no art exists, up to the full scope of the generic claim (Claim 1). *See 37 CFR § 1.146, MPEP 809.02(c), and MPEP form paragraph 8.01.*

In the present case, the Office refused to broaden the search and has mandated an improper informal restriction requirement on the claims. The Office has provided no basis in the art to avoid expanding the scope of the search to the full scope of Group I. Accordingly, the Applicants request that the Office examines the full scope of Claim 1 on the merits and provide a finding of allowance or provide rational showing why Claim 1 is unpatentable.

B. The sub-generic description provided by the Office is incorrect and outside of the scope of the claims as filed.

The sub-generic structure generated by the Office is as follows:



First, the structure above shows a tetrasubstituted phenyl on the left side of the structure. In all of the pending claims, as well as the claims as filed, the ortho position shown to be hydrogen by the Office, is required to be R³—which cannot be hydrogen. Second, in the phenyl group on the right side of the structure, the R⁴ group is located in the para position, not the meta position. R⁸ and R⁹ are accordingly out of position. Applicants request that the scope of the Office's search be broadened so that this error is not an issue.

Alternatively, the Applicants request that a corrected structure be provided showing the scope of the Office's sub-generic restriction.

II. Were Claims 7 and 9 properly rejected under 35 U.S.C. § 112?

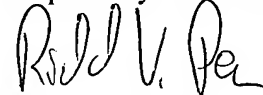
Claims 7 and 9 were rejected under § 112, as not further limiting claim 1, "since X¹ can only be sulfur and Q¹-Q⁴ *can only be carbon as drawn to the elected compounds.*" (Emphasis added). While Claim 1 does stand as objected to as containing non-elected subject matter, the scope of Claim 1 is not currently limited to X¹ being sulfur, nor is it limited to Q¹-Q⁴ being carbon. Claims 7 and 9 are both proper dependent claims placing meaningful limitations upon the claim from which they depend. Accordingly, the Applicants request that the rejection be withdrawn and Claims 7 and 9 be prosecuted on the merits.

III. Were Claims 8, 10, 12, 13, 18 and 19 properly withdrawn from consideration as being drawn to non elected subject matter under 37 CFR § 1.142(b)?

37 CFR § 1.142(b) states that "Claims to the invention or inventions **not elected**, if not canceled, are nevertheless withdrawn from further consideration by the examiner" The meaning of what subject matter can be withdrawn by the examiner under this provision is clearly spelled out in 37 CFR § 1.142(a). This section states that "If two or more independent and distinct inventions are claimed in a single application, the examiner in an Office action will require **the applicant** in the reply to that action to **elect an invention** to which the claims will be restricted, . . ." Accordingly, only subject matter which was not elected by the applicant as a result of the formal restriction requirement may be withdrawn under 37 CFR § 1.142(b). The Office supplies the groups for election (in the present case, Group I and Group II) and the Applicant elects which group to prosecute (Group I was elected). The Office may withdraw claims that read on nonelected subject matter (Group II multiple uses), but may not withdraw elected subject matter (that within the scope of Claim 1).

Claims 8, 10, 12, 13, 18 and 19 all depend from Claim 1, which is completely within elected Group I. Accordingly, it is improper for these claims to be withdrawn under 37 CFR 1.142(b). Applicants request that Claims 8, 10, 12, 13, 18 and 19 be reinstated and examined on the merits.

Respectfully submitted,



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Date: November 14, 2005

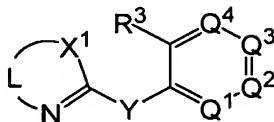
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Appendix

Copy of pending Claims

Claim 1. A compound having the structure:



or any pharmaceutically-acceptable salt thereof, wherein:

L is $-C(R^1)=C(R^2)-$ or $-C(R^2)=C(R^1)-$;

Q^1 is N or $C(R^5)$;

Q^2 is N or $C(R^6)$;

Q^3 is N or $C(R^7)$;

Q^4 is N or $C(R^6)$;

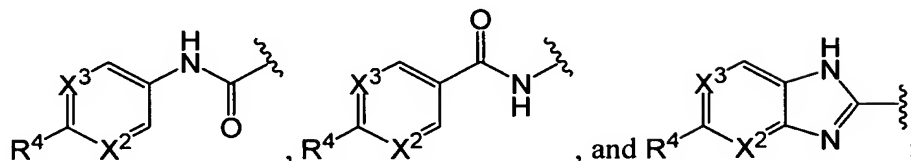
X^1 is NH, S, S=O, S(=O)₂ or O;

X^2 is N or $C(R^8)$;

X^3 is N or $C(R^9)$;

Y is NH, $C(R^{10})(R^{11})$, S, S(=O), S(=O)₂ or C(=O);

R^1 is selected from



R^2 is H, C₁₋₂alkyl, -CF₃, -NH₂, -OH, -OCH₃, F, Cl or Br;

R^3 is halo, C₁₋₆alkyl, C₁₋₄haloalkyl, -N(H)C₁₋₄alkyl, -N(C₁₋₄alkyl)C₁₋₄alkyl or -OC₁₋₄alkyl;

R^4 is Br, I, C₂₋₆alkyl, C₁₋₄haloalkyl, -C(=O)R^b, -OR^b, -(C₁₋₄haloalkyl)OH, -N(C₁₋₂alkyl)C₁₋₂alkyl or -CN; wherein if Y is CH₂ and R^3 and R^5 are both Cl, then R^4 is other than isopropyl;

R^5 is, independently in each instance, H, halo, C₁₋₆alkyl, C₁₋₄haloalkyl, -N(H)C₁₋₄alkyl, -N(C₁₋₄alkyl)C₁₋₄alkyl or -OC₁₋₄alkyl;

R^6 is, independently in each instance, H, F, C₁₋₆alkyl, C₁₋₄haloalkyl, -N(R^a)R^a, -OR^a, -S(=O)₂N(R^a)R^a, -C(=O)N(R^a)R^a, or -N(R^a)C(=O)R^b;

R^7 is H, F, C_{1-6} alkyl, C_{1-4} haloalkyl, $-N(R^a)R^a$, $-OR^a$, $-S(=O)_2N(R^a)R^a$, $-C(=O)N(R^a)R^a$, or $-N(R^a)C(=O)R^b$;

R^8 is H, halo, C_{1-6} alkyl, C_{1-4} haloalkyl, $-N(H)C_{1-4}$ alkyl, $-N(C_{1-4}$ alkyl) C_{1-4} alkyl or $-OC_{1-4}$ alkyl;

R^9 is H, halo, C_{1-6} alkyl, C_{1-4} haloalkyl, $-N(H)C_{1-4}$ alkyl, $-N(C_{1-4}$ alkyl) C_{1-4} alkyl or $-OC_{1-4}$ alkyl;

R^{10} is H, F, C_{1-6} alkyl, C_{1-4} haloalkyl, $-N(R^a)R^a$, or $-OR^a$;

R^{11} is H, F, C_{1-6} alkyl, C_{1-4} haloalkyl, $-N(R^a)R^a$, or $-OR^a$;

R^a is, independently at each instance, H or C_{1-6} alkyl; and

R^b is, independently at each instance, C_{1-6} alkyl.

Claims 2-5 (cancelled)

Claim 6. A pharmaceutical composition comprising a compound according to Claim 1 and a pharmaceutically-acceptable diluent or carrier.

Claim 7. A compound according to Claim 1, wherein Q^1 is $C(R^5)$; Q^2 is $C(R^6)$; Q^3 is $C(R^7)$; and Q^4 is $C(R^6)$.

Claim 8. A compound according to Claim 1, wherein X^1 is NH.

Claim 9. A compound according to Claim 1, wherein X^1 is S.

Claim 10. A compound according to Claim 1, wherein X^1 is O.

Claim 11. A compound according to Claim 1, wherein X^2 is $C(R^8)$; and X^3 is $C(R^9)$.

Claim 12. A compound according to Claim 1, wherein X^2 is N; and X^3 is $C(R^9)$.

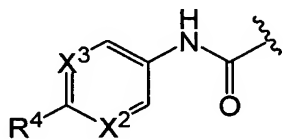
Claim 13. A compound according to Claim 1, wherein X^2 is $C(R^8)$; and X^3 is N.

Claim 14. A compound according to Claim 1, wherein Y is NH.

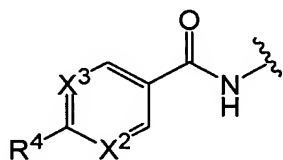
Claim 15. A compound according to Claim 1, wherein Y is C(R¹⁰)(R¹¹).

Claim 16. A compound according to Claim 1, wherein Y is CH₂.

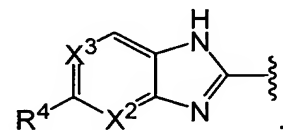
Claim 17. A compound according to Claim 1, wherein R¹ is:



Claim 18. A compound according to Claim 1, wherein R¹ is



Claim 19. A compound according to Claim 1, wherein R¹ is



Claim 20. A compound according to Claim 1, wherein R⁴ is Br, I, t-butyl, isobutyl, n-butyl, sec-butyl, ethyl, n-propyl or C₁₋₄haloalkyl.